REMARKS

In response to the Office Action mailed December 28, 2006, the Advisory Action dated March 5, 2007, and the Advisory Action dated May 29, 2007, Applicant has elected to file a Request for Continued Examination. Applicant respectfully submits the following remarks.

Claims 66-71, 73-78 and 80-118 are pending. Claims 80-118 are new. The Examiner rejected claims 66, 67, 71, 73, 74 and 78 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,820,614, issued to Bonutti. The Examiner rejected claims 68-70 and 75-77 under 35 U.S.C. § 103(a) as obvious over Bonutti in view of U.S. Patent No. 5,607,386 issued to Flam. Applicant respectfully traverses the Examiner's rejections.

Applicant previously submitted, on September 27, 2006, a declaration under 37 CFR 1.131 establishing that Bonutti is not a prior art reference under Section 102(e) or Section 103(a). Under Section 1.131, an Applicant can overcome a prior art reference by showing either (i) conception prior to the effective date and due diligence between just prior to the effective date of the reference and the date of actual or constructive reduction to practice, or (ii) actual reduction to practice prior to the effective date of the reference. Applicant chose at that time to establish conception prior to the effective date coupled with due diligence.

In an Office Action dated December 28, 2006, the Examiner contended the declaration was ineffective to overcome Bonutti because the declaration failed to establish a date of conception. The Examiner also contended a statement in a supporting document constituted an admission that there was no prior conception and no diligence. In a response filed on February 7, 2007, Applicant noted that a date of conception need not be established; Applicant need only show that conception occurred prior to the effective date of the reference. Applicant also noted that the alleged "admission" was not pertinent to whether conception occurred prior to the effective date or to whether Applicant had acted with due diligence.

On March 5, 2007, the Examiner issued an Advisory Action. In the March 5, 2007 Advisory Action, the Examiner withdrew the assertion that the declaration was ineffective because it failed to establish a date of conception prior to the effective date of the reference and the assertion that the supporting document constituted an admission regarding due diligence.

The Examiner contending in the March 5, 2007 Advisory Action that the declaration was ineffective because it in fact fails to establish due diligence.

In response, Applicant submitted a Supplemental Declaration of the Applicant establishing Applicant's actual reduction to practice prior to the effective date of the reference, as well as supporting documents and a supporting Declaration from a witness. In the Advisory Action dated May 29, 2007, the Examiner contends the Supplemental Declaration merely establishes conception, and fails to establish diligence. Applicant respectfully traverses the Examiner's contention that the Supplement Declaration merely established conception. The Supplemental Declaration, the supporting documents and Declaration from a witness establish actual reduction to practice. Actual reduction to practice prior to the effective date of the reference renders any due diligence inquiry moot. See 37 CFR 1.131(b) and MPEP 715.07 (II). Accordingly, Applicant respectfully submits that claims 66-71 and 73-78 are allowable because Applicant has establish reduction to practice prior to the effective date of the reference.

With regard to the new claims 80-118, Applicant submits the following remarks.

Conventional direct intubation involves the attempted direct insertion of an endotracheal tube together with an indwelling very thin stylett (usually metal) to facilitate placement under direct laryngoscopy. Direct laryngoscopy utilizes a laryngoscope which is a medical instrument with a long lighted handle inserted into and down a patient's throat to illuminate and visualize the patient's laryngeal inlet which is the opening to the patient's trachea. The endotracheal tube is inserted directly through the patient's vocal cords and into the patient's trachea. Direct intubation with an endotracheal tube is often difficult to accomplish in view of the size of the tube, which often limits the ability of the provider to clearly see the laryngeal inlet, particularly in small patients. Endotracheal tubes typically have an inflatable cuff, further obscuring visibility.

When conventional direct insertion of the endotracheal tube fails, an endotracheal introducer, also sometimes called a "bougie," is sometimes employed to achieve endotracheal intubation in the following manner. If direct insertion was attempted, the endotracheal tube is removed from the patient's mouth. The patient's laryngeal inlet or structures nearest to it are identified through the use of an laryngoscope in the same manner as conventional direct

endotracheal tube intubation. Then an endotracheal introducer (with no endotracheal tube attached) is passed under visual guidance by the health care provider into the patient's laryngeal inlet until proper endotracheal placement (positioning within the trachea) has been confirmed through standard medical techniques. Once the introducer is within the trachea, the provider removes the laryngoscope while keeping the introducer in position within the trachea. The provider then threads a standard endotracheal tube over the introducer. Once the endotracheal tube has been partially inserted over the introducer and the endotracheal tube's tip has passed the patient's tongue and begun to descend toward the patient's larynx, the laryngoscope is inserted back into the patient's mouth and into position near the laryngeal inlet to best visualize the patient's vocal cords and the opening into the patient's trachea. While still holding the scope with one hand a health care provider attempts with the other hand to push the endotracheal tube over the introducer toward the laryngeal inlet and through the vocal cords and past other soft tissue structures in the area of the laryngeal inlet until the endotracheal tube has been sufficiently advanced to reside within the patient's trachea. The provider then carefully removes the introducer leaving the endotracheal tube in place.

The are several problems with the conventional endotracheal introducer approach. The introducer is thin (about 5 mm) and provides a very small purchase point for the health care provider to grasp and attempt to control the introducer during a life saving procedure that must be performed quickly and without puncturing the patient. The introducer must remain thin along its entire length so that the endotracheal tube can be inserted over the introducer. Additionally, using a conventional introducer requires inserting a laryngoscope, removing the laryngoscope, partially sliding an endotracheal tube over the introducer, reinserting the laryngoscope, and then pushing the endotracheal tube over the introducer into the trachea. The conventional use of an introducer also makes it difficult to insert and advance the subsequently added endotracheal tube past all the soft tissues around the laryngeal inlet and into the trachea.

An embodiment of the current invention alleviates many of the problems arising from conventional intubation devices and approaches. The novel use of a retention device or coupler to secure an endotracheal tube onto a placement device with a bendable portion of the placement device extending out of the endotracheal tube is significantly superior, and provides

unexpected advantages. All or portions of the placement device can be bendable. The portion of the placement device extending out of the endotracheal tube also can be small in cross-section to facilitate visualizing of the soft tissues around the laryngeal inlet as the portion of the placement device is inserted, while the endotracheal tube, which is secured to the placement device with the retention device, has a larger cross-section, providing for an larger point from which to hold and maneuver the placement device. The addition of a secured endotracheal tube on the placement device also increases the balance of the placement device, providing for better control of the tip of the placement device as it is maneuvered into position in the patient's trachea. The retention device itself can act as a handle. In fact, a handle can be added to the placement device since it is no longer necessary to slide the endotracheal tube onto the placement device during an intubation. The tip of the placement device can be more easily viewed than a tip of a directly inserted endotracheal tube, and the end of the placement device is more easily maneuvered into position in the patient's trachea than an end of a conventional endotracheal introducer. Additionally, embodiments of the device avoid having to remove the laryngoscope and then reinsert the laryngoscope back into position, saving the both valuable time and avoiding the complexity of having to reinsert the laryngoscope back into proper position along with the possible resulting complications and trauma to the patient. Embodiments of the device also may be inexpensive, without requiring the use of additional equipment to view an image and/or to hold the stylet and endotracheal tube (and any other components) in the proper position.

Previously, the Examiner cited U.S. Patent No. 5,607,386 issued to Flam, referenced above. Applicant respectfully submits that Flam is not an appropriate anticipating or primary reference to the claims of the present application, whether considered alone or in combination with Bonutti. U.S. Patent No. 5,607,386 issued to Flam is an example of a device configured for conventional direct insertion of the endotracheal tube. Flam addresses the visibility problem by including a fiber optic cable within the endotracheal tube. This is an expensive solution to the problem, requiring additional equipment to display an image, further increases the size of the tube (reducing direct visibility and limiting the patients in which the device of Flam can be used), and is not a practical solution for many environments and situations.

Specifically, Flam discloses a stylet 12, which is not configured to extend out of the endotracheal tube 24. Instead, the stylet 12 of Flam is recessed within the endotracheal tube 24. See, e.g., Figure 2 and the description at Column 8, lines 8-12. One would not be motivated to extend the stylet 12 out of the endotracheal tube 24 because the stylet 12 is not configured to introduce the instrument 10 of Flam through vocal cords. Indeed, modifying the stylet 12 of Flam to extend out of the endotracheal tube 24 would create a high risk of puncture. Further, Flam teaches away from adding an endotracheal placement device because Flam employs a fiberoptic bundle 21, so that an image of the vocal cords may be viewed on an external screen. The fiber optic bundle 21 of Flam also is recessed, in this case into the stylet 12, at least until after the endotracheal tube 24 has cleared the vocal cords. See Flam, Column 8, lines 39-50. Applicant submits that new claims 80-118 are not anticipated or rendered obvious by Flam, alone or in combination with Bonutti.

Accordingly, all of the current claims are allowable. In the event the Examiner disagrees or has any concerns, Applicant respectfully requests an interview with the Examiner to discuss the allowability of the current claims over the references cited to expedite prosecution of the present application. Applicant will contact the Examiner after the Examiner has had a chance to review the current claims to schedule an interview.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090. All of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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